

Washington State Institutional Review Board

REVIEW PROCESS

Applications

Research proposals are submitted to the DSHS Human Research Review Section, which provides administrative support to the Washington State Institutional Review Board (WSIRB). Application forms are posted on the Human Research Review Section's website (<http://www1.dshs.wa.gov/rda/hrrs/>). An electronic copy of each proposal requiring full-Board review must be submitted to the Review Section's email address (wsirb@dshs.wa.gov) by the published deadline date for each scheduled Board meeting. Review Section staff will notify investigators within one week if they should submit twenty paper copies of the proposal for distribution to the full-Board. Electronic and paper copies of proposals that qualify for expedited review may be submitted to the Review Section at any time.

Pre-Review Process

All proposals that require full Board review go through a pre-review process. Pre-review is intended to determine if the proposal is complete, responsive to instructions in the application forms, and ready for full Board review with a low chance of being held in abeyance. Review Section staff will ask one Board member to serve as the "primary reviewer" of the proposal. In some instances, a "secondary reviewer" also will be assigned. The electronic copy of the proposal will be forwarded to the primary reviewer and a telephone conference scheduled within five working days of receipt of the proposal. At the pre-review conference, Review Section staff and the primary reviewer will assess the proposal and make the following determination:

- If the proposal is found generally ready for full-Board review but requires some clarification and supplemental information, Review Section staff will notify the investigator to submit twenty paper copies of the proposal to the Review Section. Review Section staff also will provide detailed feedback to the investigator and request a written addendum to the proposal which addresses the issues and questions identified in the pre-review.
- If the proposal is found not ready for full Board review because it is incomplete, not responsive to instructions in the application forms, and/or confusing or inconsistent, Review Section staff will notify the investigator of the need to revise the proposal before it will be accepted for full-Board review. Review Section staff will provide the investigator with a detailed list of issues that need to be addressed and incorporated into the revised proposal.

Investigators will be allowed seven calendar days to submit an electronic copy of the study addendum or revised proposal to the Review Section. The response will be screened by Review Section staff, and if found acceptable, the proposal with the addendum, or the revised proposal, will be distributed to Board members at least one week before the scheduled meeting.

Expedited Reviews

If a proposal meets the criteria for expedited review (Washington State Agency Policy.... Section X), Review Section staff will ask one or more Board members to review the proposal. A telephone conference call is scheduled for the reviewers to discuss the proposal and reach a disposition decision. A copy of the application summary page (Form A) and the Review Board's disposition correspondence to the researcher is placed on the agenda of the next Board meeting and is provided to all Board members.

Full Board Reviews

Copies of research proposals and study amendments requiring "full Board" review, progress reports for continuation approval, summary information and initial correspondence regarding expedited reviews, and other review materials and information are mailed to all Board members about one week before each scheduled meeting. Board members are expected to read each proposal carefully in advance and to note their scientific, ethical, legal, and other concerns for discussion at the Board meeting. Board members are encouraged to refer to the "Review Criteria" in this handbook and to use the *Review Worksheet* when reviewing new proposals, particularly those which require full-Board review. *Review Worksheets* are enclosed with the Board materials for each full Board meeting. A *Presentation Guide* which summarizes the study, lists the review questions or concerns, assesses the risks and benefits, and documents the disposition recommendation, is available for primary reviewers. Primary reviewers are required to submit a copy of their disposition recommendation and approval conditions or review issues to Review Section staff at or before the Board meeting. The *Review Worksheet* and *Presentation Guide* are posted on the Review Section's website.

WSIRB Rules of Order, adapted from Robert's Rules in Plain English, are followed during full Board meetings. Following presentation of a proposal, the primary reviewer is asked to make a motion for disposition of the proposal. After a motion is made and seconded, other Board members may ask for the floor and make their comments without interruption. The Board Chair may then open the floor to general discussion. After deliberation, the Chair, with the assistance of Review Section staff, will restate the motion, including any additions and amendments, before the formal vote is taken. Disposition of the proposal is determined by a simple majority vote of members present. If the motion does not pass, the floor is open to disposition motions introduced by other Board members.

The Board may make any of the following decisions regarding a proposal under review:

- **Approved:** The proposal can be approve as submitted or amended prior to the meeting.
- **Conditionally Approved:** Simple concurrence of the investigator to a specified set of conditions is all that is required for approval of the proposal. Final approval is delegated to a subcommittee; no need for review at another meeting.¹

¹ Approval can be delegated to a Board subcommittee when research is "not more than minimal risk" (See definition of "minimal risk" in the Washington State Agency Policy...Section IV.) or when approval requires only verification that the investigator has agreed to all the Board's approval conditions.

- **Held in Abeyance:** The number of issues, concerns and/or questions are too significant to be resolved by the simple concurrence of the investigator. The proposal must go back to another meeting.
- **Disapproved:** This should be decided only after the investigator has been invited to a meeting to resolve serious issues, and further attempts to negotiate required revisions would be fruitless. While this disposition effectively terminates further review of the proposal, the investigator is free to appeal the Board's decision or submit a new proposal for consideration at a later meeting

Outside Consultation

If a proposal requires expertise beyond those represented on the Board, the Review Section staff may seek verbal advice or written consultation from outside research professionals. Copies of the professional's viewpoint will be distributed to all Board members. Consultation with outside experts should preserve the anonymity of the researcher, or if this is not possible, should be conducted in a confidential manner. When consultation is obtained, however, the Board remains responsible for independently determining the scientific and ethical acceptability of the proposal. If a proposal is unusually complicated, or if considerable uncertainty or concerns exist about critical aspects of the research, the researcher may be invited to attend the Board meeting to provide additional information or to respond to specific review concerns. The researcher must leave the meeting prior to the disposition vote by the Board.

Board Correspondence

The Board's disposition decision and any remaining review issues and/or required modifications are communicated in writing to the researcher by the Executive Secretary or the Associate Executive Secretary. For proposals reviewed at convened meetings, the primary reviewer is asked to review and comment on draft Board correspondence before it is mailed to the researcher. While primary reviewers are encouraged to contact research applicants in the course of preparation for the Board meeting, only the Executive Secretary, Associate Executive Secretary, or the Board Chair should communicate with researchers following the Board's formal review of expedited and full Board reviews.

Progress Reports

The *maximum* period of approval for a study is one year. Prior to expiration of study approval, researchers must submit a progress report for continuation review and approval. Review Section staff notifies researchers when their progress reports are due. Electronic progress report forms are available on the Review Board's website. The progress report should describe activities to date, study amendments, study participation, adverse events or other problems, remaining activities, and the anticipated completion date. Progress reports for research that initially underwent expedited review, and for research that underwent full-Board review but in which all contacts with subjects are completed, are reviewed through expedited procedures. For research that required full Board review, the primary reviewer is expected to present the progress report at the Board meeting. Primary reviewers also may be asked to review, and possibly to present in a Board meeting, study amendments submitted by researchers after the research has been approved.